PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	**FOR FURTHER ACTION** see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
99.70446/001		
International application No.	International filing date *(day/month/year)*	(Earliest) Priority Date *(day/month/year)*
PCT/EP 00/ 05831	23/06/2000	23/06/1999
Applicant		
CAMBRIDGE CONSULTANTS LIMITED et al.		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

   a. With regard to the **language,** the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

   [ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

   b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

   [ ] contained in the international application in written form.

   [ ] filed together with the international application in computer readable form.

   [ ] furnished subsequently to this Authority in written form.

   [ ] furnished subsequently to this Authority in computer readble form.

   [ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   [ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (see Box II).

4. With regard to the **title,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract,**

   [X] the text is approved as submitted by the applicant.

   [ ] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 2

   [X] as suggested by the applicant.

   [ ] because the applicant failed to suggest a figure.

   [ ] because this figure better characterizes the invention.

   [ ] None of the figures.

cyclone (1) is mounted on the plunger (19).

PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

DIXON, Philip Matthew
FRANK B. DEHN & CO.
179 Queen Victoria Street
London EC4V 4EL
GRANDE BRETAGNE

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	27.03.2001
Applicant's or agent's file reference 99.70446/001	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/05831	23/06/2000	23/06/1999

Applicant
CAMBRIDGE CONSULTANTS LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/	Authorized officer
European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Terzic, K Tel.+49 89 2399-2052

Form PCT/IPEA/416 (July 1992)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
99.70446/001		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP00/05831	23/06/2000	23/06/1999
International Patent Classification (IPC) or national classification and IPC A61M15/00		
Applicant CAMBRIDGE CONSULTANTS LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 6 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
23/01/2001	27.03.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Weber, P Telephone No. +49 89 2399 2873

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP00/05831

I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).)*:
Description, pages:

1,2,4,8-10	as originally filed			
3,5-7	as received on	23/01/2001	with letter of	22/01/2001

Claims, No.:

1-6	as received on	23/01/2001	with letter of	22/01/2001

Drawings, sheets:

1/3-3/3	as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   - ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   - ☐ the language of publication of the international application (under Rule 48.3(b)).
   - ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   - ☐ contained in the international application in written form.
   - ☐ filed together with the international application in computer readable form.
   - ☐ furnished subsequently to this Authority in written form.
   - ☐ furnished subsequently to this Authority in computer readable form.
   - ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   - ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-6
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-6
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-6
	No:	Claims	

2. Citations and explanations
   see separate sheet

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. The closest prior art inhaler is considered to be disclosed in US-A-5476093 (D1). The inhaler according to Claim 1 is an alternative construction to the one of D1. This alternative construction can be made smaller and the spring powered plunger of the pump cylinder is easier to use for the patient who does not have to activate the pump by hand.

This alternative construction is not suggested by the cited prior art documents. In particular the dimension of the cylindrical cavity goes against the teaching of D1 in which an optimum diameter of 10 to 20 mm is mentioned, and the association of a cyclone and a piston pump with a spring-powered plunger in an inhaler according to the preamble is not suggested either.

Thus, Claim 1 fulfils the requirements of Art.33(2)(3) PCT.

2. Claims 2 to 6 concern developments of the invention according to Claim1, so that they also fulfil the requirements of Art.33(2)(3) PCT.

3. Industrial applicability is self-evident.

effects if the proportion of the emitted dose which is not respired is swallowed.

Thus, it is important for the systemic delivery of medicaments by inhalation that a repeatable dose of fine particles can be produced.

It is known for so-called "spacers" to be used in the generation of the aerosol from a metered dose inhaler. The spacer fits onto the mouthpiece of the inhaler and comprises a chamber into which the dose of medicament is ejected by the inhaler. The patient is then able to inhale the dose from the spacer through a corresponding mouthpiece on the spacer.

Large volume spacers are used where the patient is unable to inhale at the same time as operating the metered dose inhaler due to a lack of coordination. Small volume spacers are used to trap large particles which would stick to the back of the throat and may cause undesirable side-effects.

The present invention, at least in its preferred embodiments, seeks to provide an inhaler for generating an inhalable aerosol of a powdered medicament with an effective particle size that is sufficiently small for the medicament to be delivered to and absorbed in the lungs of a patient.

Thus, viewed from a first aspect the invention provides an inhaler comprising:

a chamber having a mouthpiece;

a cyclone arranged to eject an aerosol of medicament into the chamber; and

a drug dosing device arranged to provide a dose of powdered medicament entrained in an airflow to the cyclone.

In use of the inhaler, the powdered medicament is entrained in an airflow by the drug dosing device and expelled through the cyclone into the chamber as an aerosol for subsequent inhalation by a patient.

Thus, the invention provides a simple arrangement

US-A-5,476,093 discloses an inhaler according to the preamble of claim 1. The inhaler of the invention is distinguished over this disclosure by the characterising features of claim 1.

the cyclone comparable in volume to the cyclone itself to act as a diffuser. Similarly, a spacer may be provided at the outlet of the cyclone to act as a diffuser.

A plurality of cyclones may be provided such that their outlet flows coincide and interfere with each other to create extra shear forces.

The airflow to the drug dosing device ~~may be provided by an external air source, for example a source of compressed air. In a preferred arrangement, however, the airflow~~ is provided by a pump in the inhaler. Thus, the inhaler ~~may~~ comprises a pump. ~~The pump may be in the form of, for example, a piston pump, a resilient bladder or a source of compressed gas, such as a gas canister.~~ Preferably, the pump is arranged to provide an airflow of repeatable volume and velocity. Thus, the pump ~~may~~ takes the form of a spring-powered piston received in a cylinder.

It has been identified that a problem associated with inhalers of the type according to the invention is that when the aerosol is expelled into the chamber, the aerosol tends to interact unfavourably with the air in the chamber. It is known for the chamber to be open and for the air initially within the chamber to be expelled through the mouthpiece of the chamber as the aerosol is introduced through a nozzle. However, this has been found to be unsatisfactory as the amount of medicament which escapes through the mouthpiece before the user inhales is unquantifiable.

Thus, ~~viewed from a further aspect,~~ the invention may further provides an inhaler comprising:

a chamber having a mouthpiece; and

an aerosolising device having an inlet for taking in an airflow and an outlet for expelling an aerosol into the chamber, wherein the inlet of the aerosolising device is connected to the chamber, such that, in use, the airflow is drawn from the chamber to generate the

aerosol.

Thus, according to this ~~aspect of the invention~~ feature, air from within the chamber passes through the aerosolising device to generate the aerosol so that the chamber can be filled with aerosol without expelling air, and potentially medicament, through the mouthpiece of the chamber.

The aerosolising device ~~may~~ comprises a cyclone and ~~or~~ a drug dosing device as previously described. The aerosolising device may also comprise a pump arranged to draw air from the chamber via the inlet.

In one arrangement, the chamber receives a plunger which is arranged to force air through the aerosolising device as the plunger moves through the chamber. In a particularly preferred embodiment, the aerosolising device is mounted on the plunger.

Thus ~~viewed from a yet further aspect~~ the invention may provides an inhaler comprising a chamber having a mouthpiece and a plunger received in the chamber, wherein the plunger is arranged to force air through an aerosolising device to generate an aerosol of medicament in the chamber for inhalation through the mouthpiece.

Some embodiments of the invention will now be described by way of example only and with reference to the accompanying drawings, in which:

Figure 1 shows a cyclone for use in the invention;

Figure 2 shows a first embodiment of the invention;

Figures 3 shows a second embodiment of the invention;

Figure 4 shows a third embodiment of the invention;

Figure 5 shows a fourth embodiment of ~~the~~ invention; and

Figure 6 shows a fifth embodiment of the invention;

Corresponding reference numerals have been used for corresponding parts in each embodiment of the invention.

Figure 1 shows a cyclone 1 for use in aerosolising a powdered medicament according to the invention. The

cyclone 1 is in the form of a cylinder 3 of a diameter ~~between about 2 and 15 mm, preferably~~ between 4 and 10 mm. The cylinder 3 is closed at an input end and provided with a frustoconical portion 5 at an output end. The cyclone 1 has an inlet 9 in the region of the closed input end of the cylinder 3, which input 9 is substantially tangential to the wall of the cylinder 3. The frustoconical portion 5 has an outlet 7 defined therein, which outlet 7 is concentric with the axis of the cylinder 3.

In use, an airflow entrains a powdered medicament and enters the cyclone 1 through the tangential inlet 9, as indicated by arrows A. The airflow (and medicament) is directed by the internal surface of the cylinder 3 in a helical path towards the outlet 7. The frustoconical portion 5 of the cyclone 1 narrows the radius of the helical path, thereby increasing the speed of the airflow and increasing the shear forces on the entrained medicament. Consequently, an aerosol of powdered medicament having particles of respirable size issues from the outlet 7 of the cyclone 1, as indicated by arrows B.

Figure 2 shows a first embodiment of the invention. According to this embodiment a cyclone 1 is connected to a chamber 11 having a mouthpiece 13. The chamber has a volume of around 300 ml. The cyclone 1 is located at an end of the chamber 11 opposite the mouthpiece 13, and the outlet 7 of the cyclone 1 is arranged to eject the aerosol of medicament into the chamber 11 towards the mouthpiece 13, as indicated by arrows B.

A drug dosing device 15 is connected to the inlet 9 of the cyclone 1 and is arranged such that, as a flow of air passes through the dosing device 15, a controlled dose of medicament is entrained in the airflow.

The airflow to the drug dosing device 15 is provided by a pump 17, which comprises a plunger 19 received in a pump cylinder 21 and biased towards an

Claims

1. An inhaler comprising:

a chamber (11) having a mouthpiece (13);

a cyclone (1) configured as a substantially cylindrical cavity (3) provided with a tangential inlet (9) and an axial outlet (7) arranged to eject an aerosol of medicament into the chamber (11);

a drug dosing device (15) arranged to provide a dose of powdered medicament entrained in an airflow to the cyclone (1); and

a pump (17) for providing the airflow to the drug dosing device (15),

characterised in that

the diameter of the cylindrical cavity is between 4 and 10 mm, and

the pump (17) is a piston pump comprising a spring-powered plunger (19, 25) received in a pump cylinder (11, 21).

2. An inhaler as claimed in claim 1, wherein the chamber (11) is comparable in volume to the cyclone (1).

3. An inhaler as claimed in claim 1, wherein the chamber (11) has a volume of around 300 ml.

4. An inhaler as claimed in any preceding claim, wherein the inlet (9) of the cyclone (1) is connected to the chamber (11), such that, in use, the airflow is drawn from the chamber (11) to generate the aerosol.

5. An inhaler as claimed in any preceding claim, wherein the chamber (11) receives the plunger (19) which is arranged to force air through the cyclone (1) as the plunger (19) moves through the chamber (11).

6. An inhaler as claimed in claim 5, wherein the

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
4 January 2001 (04.01.2001)

PCT

(10) International Publication Number
WO 01/00262 A1

(51) International Patent Classification[7]: A61M 15/00

(21) International Application Number: PCT/EP00/05831

(22) International Filing Date: 23 June 2000 (23.06.2000)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
9914722.5 23 June 1999 (23.06.1999) GB

(71) Applicant *(for all designated States except US)*: CAMBRIDGE CONSULTANTS LIMITED [GB/GB]; Science Park, Milton Road, Cambridge CB4 4DW (GB).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: HARMER, Quentin, John [GB/GB]; 16 Station Road, Waterbeach, Cambridge CB5 9HT (GB). EASON, Stephen, William [GB/GB]; The Priory, Half Moon Lane, Redgrave, Diss, Norfolk IP22 1RX (GB). SARKAR, Matthew, Neil [GB/GB]; 33 Linden Close, Cambridge CB4 3JU (GB).

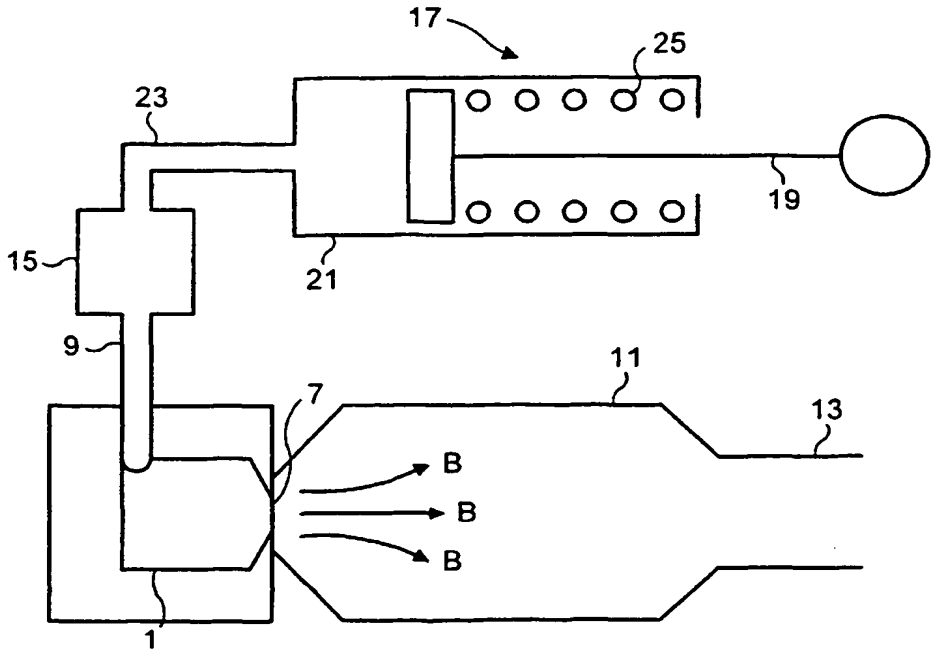
(74) Agent: DIXON, Philip, Matthew; Frank B. Dehn & Co., 179 Queen Victoria Street, London EC4V 4EL (GB).

(81) Designated States *(national)*: AE, AG, AL, AM, AT, AT (utility model), AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CR, CU, CZ, CZ (utility model), DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, EE (utility model), ES, FI, FI (utility model), GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KR (utility model), KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SK (utility model), SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: INHALERS



(57) Abstract: An inhaler comprises a pump (17), a drug dosing device (15) and a cyclone (1) which delivers an aerosol of powdered medicament from the drug dosing device (15) into a chamber (11) when the pump (17) is activated. The aerosol is inhaled by the user through a mouthpiece (13).

WO 01/00262 A1

Published:
— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International Application No
/EP 00/05831

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M15/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 3 809 084 A (HANSEN L) 7 May 1974 (1974-05-07) column 5, line 25 - line 50; claim 1; figures	1
X	WO 92 04066 A (BISGAARD HANS) 19 March 1992 (1992-03-19) page 2, line 25 - line 30; claims 1,2; figures 1,2	1,2,10
X	US 4 907 583 A (WETTERLIN KJELL I L ET AL) 13 March 1990 (1990-03-13) column 3, line 12 - line 46; figures 1,2	1,2
X	US 5 579 760 A (KOHLER DIETER) 3 December 1996 (1996-12-03) column 7, line 28 -column 10, line 47; figures 2-4C	7-9

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
11 October 2000	19/10/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Villeneuve, J-M

1

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International Application No
[redacted]/EP 00/05831

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 476 093 A (LANKINEN TAPIO) 19 December 1995 (1995-12-19) column 6, line 41 -column 8, line 2; figures	1-4
A	DE 27 22 701 A (SCHERING AG) 23 November 1978 (1978-11-23) claims; figure 1	1
A	US 3 980 074 A (WATT PETER RIDGWAY ET AL) 14 September 1976 (1976-09-14)	
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1

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
/EP 00/05831

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
/EP 00/05831

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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